

the steps of method claims 3-4 and 24, would be obvious in view of the references applied. A brief analysis of each of the references relied on by the Examiner is set forth below.

Senter et al. disclose a spinal disk implant having a pair of opposing posterior ledges where at least one of the ledges includes a pattern of serrations on its face and where the implant is composed of a ceramic, for example hydroxyapatite.

Heggeness et al. disclose prosthetic devices for insertion into intervertebral disc spaces where the device has defined contours designed to accommodate the morphological anatomy of the vertebral endplates and is composed of a durable material including metal, metal alloys, and ceramics (see col. 11, paragraph 3), that will better endure the forces exerted upon it by the adjacent vertebral bodies, where the material contains osteoinductive factors including bone growth factors.

Wagner et al. disclose a spinal disk implant having a substantially rectangular body and a central region having three-dimensional features, where the implant is composed of a biocompatible synthetic material such as a ceramic, a metal, a polymer, and a composite (see col. 3, paragraph 1).

Cottle discloses an inter-vertebral implant having a frame-like cage enclosing a space with a top and a bottom surface which can be textured, composed of titanium, titanium alloy, ceramic, or a biocompatible plastic, for example polyethylene.

McKay discloses a reinforced porous spinal implants having two opposing faces where the faces are optionally textured, a void central area, and side walls that are perforated, where the implant is composed of bioceramics.

Gross et al. disclose an intervertebral implant that is a disc-shaped spacer made of a rigid material having a dome-shaped central area, and optionally textured opposing faces. In view of the following, this rejection is respectfully traversed.

The present invention as claimed in claims 1-26, is directed to a textured bone allograft including a plurality of closely spaced protrusions and a method for making same. It is submitted that the Examiner has not established a proper case of *prima facia* obviousness. A proper case of *prima facia* obviousness under 35 U.S.C. §103, requires that the prior art as a whole, must suggest

the desirability of making the claimed combination and provide a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 5USPQ2d 1529 (Fed. Cir. 1988). The *Dow* court further held that "In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention." The court in *In re Gurley*, 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994), held that "A prior art reference may be said to *teach away* when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." The court in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986), held that "A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered."

In the present case, none of the prior art references, taken alone or together, suggest the desirability of making an implant composed of allograft bone, let alone the combination of an allograft implant and a surface having a plurality of closely spaced protrusions, as required by the present claims. All of the references cited by the Examiner, are directed to synthetic implants composed of, for example, bioceramics, metal, or metal alloys. Further, none of the references, taken alone or together, provide a reasonable expectation of success. Specifically, none of the references suggest that an allograft implant having a textured surface would successfully achieve the desired results, such results including for example, sufficient mechanical strength, ie. no "crushing" of the protrusions or projections and/or no crushing or absorption of the implant; mechanical stability, ie. no slippage or rotation of the implant; no increased risk of infection or immune response; achieve fusion; and adequate support. In fact, each of McKay, Cottle, Senter et al., Hegeness et al. and Wagner et al., teach that such results cannot be achieved with an allograft bone implant.

McKay, Cottle, Senter et al., Hegeness et al. and/or Wagner et al. each *teach away* from allograft bone, because each teach that the use of allograft bone is disadvantageous. McKay *teaches away* from the use of prior art allograft bone because McKay states that allogenic bone increases the risk of infection, increases the immune response, and provides only temporary support. Thus, to overcome the problems of allograft bone, McKay teaches the use of bioceramics. Cottle *teaches away* from "prior art" implants because "...all of these have the disadvantage that they harbor the risk of the implant sinking into the end plates of the affected vertebrae." Senter et al. *teach away* from the use of allograft bone because "...there is the increased difficulty with graft rejection and the risk of transmitting communicable diseases." Senter et al. also state that "bone" implants "...may not be perfectly shaped and placed, leading to ...or absorption of the implant, or failure of the implant to fuse with the vertebrae." Hegeness et al. *teach away* from prior art devices including allografts because "...these devices contact only a minimal number of points on the surfaces of the vertebral endplates. Such an uneven distribution of stress exerted by the adjacent vertebrae upon the devices further results in an increased risk of subsidence and collapse of the device." Hegeness et al. further state at col. 3, 1st paragraph, that "...bone grafts do not always heal reliably, with some studies reporting failure rates ...ranging from 10% to as high as 40%. Without complete bone fusion of the vertebral endplates with the intervertebral device or graft, the vertebrae adjacent to the device or graft is less stable, often necessitating further surgery..." Wagner et al. *teach away* from the use of allograft bone because "...there is the increased difficulty with graft rejection and the risk of transmitting communicable diseases."

Accordingly, one of ordinary skill in the art to which the present invention applies, in view of McKay, Cottle, Senter et al., Hegeness et al., Gross et al., and/or Wagner et al., would not be motivated to make an implant out of allograft bone, let alone an implant made out of allograft bone having a plurality of closely spaced protrusions, as required by the present claims. None of McKay, Cottle, Senter et al., Hegeness et al., Gross et al., and/or Wagner et al., taken alone or together, suggest the desirability of making an implant composed of allograft bone, let alone the claimed

combination of an allograft implant having a plurality of closely spaced protrusions. Further, none of the cited references, taken alone or together, provide a reasonable expectation of success. In fact, each of McKay, Cottle, Senter et al., Hegeness et al. and/or Wagner et al., *teach away* from an implant composed of allograft bone.

Gross et al. do not cure the deficiencies of McKay, Cottle, Senter et al., Hegeness et al. and/or Wagner et al., because Gross et al. also do not suggest an implant composed of allograft bone, let alone an allograft having a plurality of closely spaced protrusions, as required by the inventive claims. Rather, Gross et al. disclose a synthetic implant.

In view of the above, It is submitted that a proper case of *prima facie* obviousness has not been established, and that nothing in any of the cited references, taken alone or together, suggest claims 1-26 within the meaning of 35 U.S.C. §103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

It is submitted that claims 1-26 are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her Virginia Beach, Virginia telephone number on any questions that may arise.

Respectfully submitted,
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